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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,096	11/19/2001	Anke Rattenholl	13028-002001	2974

26161 7590 04/03/2006

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,096	RATTENHOLL ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-7,9-19 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/06 has been entered.

2. Newly submitted claims 21-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Similar to the reasons made of record in the restriction requirement in Paper No: 20040920, claims 21-25 are directed to *methods* of making proNGF recombinantly followed by denaturation and renaturation, and therefore, are part of the Group I *method*, which was not elected. As previously made of record no special technical feature exists for Group I (or Group II), and therefore, Group I (or Group II) still do not define a contribution over the prior art. Again, PCT Rule 13 does not provide for multiple products or methods within a single application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Applicant's arguments filed 1/3/06 and 1/12/06 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 8 & 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the recitation ""the proNGF having activity of a level comparable to that of β-NGF". In contrast to Applicants' assertions on page 5 of the 1/3/06 response, no such basis exists on pages 22-23 of the specification. In contrast, the first sentence of page 23 states "the biological activity of mature β-NGF is about twice as high as that of rh proNGF" in the dorsal root ganglion assay; thereby, clearly constituting new matter.

6. Claims 8 & 20 stand rejected under 35 U.S.C. 102(b) as anticipated by Edwards et al (U.S. Patent 5,683,894), for the reasons made of record in Paper NOs: 20050124 & 20050706, and as follows.

Applicants argue on pages 5-6 of both the 1/3/06 & 1/12/06 responses that "Edwards discloses only crude compositions containing proNGF", and refers to column 7 and Example 4 of Edwards. In contrast to Applicants' assertions, and as previously made of record, the claims recite open claim language (i.e., "comprising"), in which even crude compositions in a pharmaceutically acceptable carrier still meets the limitations claimed; especially when the instant specification fails to define any other definition for "pharmaceutical preparation", and in which column 8 (lines 4-6) alternatively states that "lysates were *cleared of particulate material* by centrifugation... in a microcentrifuge to provide a *pro-NGF solution* (i.e., in 50mM NaCL/100mM Tris (pH7.6)); thereby, no longer being just a crude preparation. As also previously made of record, Edwards et al specifically teach a pharmaceutical composition containing recombinant pro-NGF-beta solution (col. 8, Example 5C & D; col. 5 (lines 23-26); col. 7, Example 2) *before digestion* "for comparison with active NGF-beta" (col. 7, lines 9-10), in which polyacrylamide gel (Example 5) is further a well known pharmaceutically acceptable excipient for administration to animals to generate antibodies (e.g., as it relates to Applicants' comments on page 6 of the response). As previously made of record, pharmaceutical carriers are further described in column 10 (e.g., phosphate buffered saline (PBS)). As also previously made of record, although Applicants are correct that column 9 states that a given proNGF preparation "exhibited little... activity" (i.e., "supernatant from L929/VV:NGF-A and L929/W:NGF-b (non-digested)", other "preparations" of proNGF are disclosed by Edwards, which still are structurally identical with that claimed; thereby, reasonably possessing any recited "activity" level (e.g., as recited in claim 8). Therefore, Applicants' arguments are not persuasive for that currently

claimed, because the description of a proNGF solution in 50 mM NaCL/100mM Tris (pH7.6) is a pharmaceutical preparation, by definition.

Applicants then argue that "[t]he Office speculates that the activity associated with any proNGF is merely due to cellular cleavage of proNGF into β-NGF by target cells... [and] that cells will naturally and automatically process the pro-drug, proNGF, into a more active molecule/ ingredient". *In arguendo,* this was an alternative argument presented by the Examiner and does not change the fact that Edwards teaches the proNGF *product* in solution (i.e., a pharmaceutical preparation), which is structurally identical with that claimed; consistent with that held by the courts in *In re Thorpe, In re Marosi, Ex parte Gray, In re Best* and *In re Brown*, previously made of record.

Accordingly, the Susan Lorey Declaration under 37 CFR 1.132 filed 1/3/06 is insufficient to overcome the rejection of these claims based upon Edwards as set forth in the last Office action because Edwards still teaches proNGF in solution (i.e., a pharmaceutical preparation). However, the Lorey Declaration is persuasive for establishing that proNGF is an "active ingredient" within its own right, and not the same as a pro-drug, in which the active ingredient would then be NGF after processing *in vivo* (i.e., "evergreening" a previously known drug; as it relates to the Examiner's alternative argument). However, it should be noted, in regards to Applicants' arguments concerning "scientific reports... published six years after the instant inventions was made", that the court in *In re Hogan and Banks*, 194 USPQ 527 (1977) makes clear that "enablement must be established in the specification *at the time of filing* and is to be *commensurate in scope* with the stated claims [emphasis added]".

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
March 23, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER